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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/349,489 12/02/94 RING

D 0999.001  
EXAMINER

18N1/0329

PAUL B SAVEREIDE  
CHIRON CORPORATION  
INTELLECTUAL PROPERTY R440  
P O BOX 8097  
EMERYVILLE CA 94662-8097

ART UNIT PAPER NUMBER

1806

DATE MAILED:

03/29/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been ~~examined~~ **RESTRICTED** ☐ Responsive to communication filed on ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 0 month(s), 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/>   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-15 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☐ Claims \_\_\_\_\_ are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☒ Claims 1-15 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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**Part III DETAILED ACTION**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-4, and 15 drawn to the process of inducing an immune response using bispecific antibodies specific for self antigens, classified in Class 530 subclass 387.3 and Class 424, subclasses 136.1, 144.1.

Group II. Claims 1-3, 5-9, and 15, are drawn to the process of inducing an immune response using bispecific antibodies specific for cancer antigens, classified in Class 530 subclass 387.7 and Class 424, subclasses 136.1, 138.1, 155.1, 156.1 and 174.1.

Group III. Claims 1-3, 10, 11, and 15, drawn to the process of inducing an immune response using a bispecific antibodies specific for viral antigens, classified in Class 530 subclass 388.3 and Class 424, subclasses 136.1, 147.1, 159.1, 160.1, 161.1.

Group IV. Claims 1-3, 12 and 15, drawn to the process of inducing an immune response using bispecific antibodies specific for fungal antigens, classified in Class 530 subclass 388.5 and Class 424, subclasses 136.1 and 274.1.

Group V. Claims 1-3, 13 and 15, drawn to the process of inducing an immune response using bispecific antibodies specific

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for parasitic antigens, classified in Class 530 subclass 388.6  
Class 424, subclasses 136.1, 151.1, 265.1.

Group VI. Claims 1-3, 14, and 15, drawn to the process of inducing an immune response using a bispecific antibodies specific for toxins, classified in Class 424, subclasses 136.1, 150.1, 163.1, 164.1, 177.1, 236.1.

2. Inventions I-VI are related as processes of inducing an immune response. The inventions use different reagents and have different objectives and parameters. Invention I is directed to a self antigen. Invention II is directed to tumor antigens. Invention III is directed to viral antigens. Invention IV is directed to fungal antigens. Invention V is directed to parasitic antigens. Invention VI is directed to toxins. In the instant case the combinations are not related and are deemed patentably distinct. Furthermore, because these inventions are distinct, have acquired a separate status in the art, as shown by their different classification, and require different searches, restriction for examination purposes as indicated is proper.

3. Upon election of Group II, further elections of species are required as follows:

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Bispecific antibodies comprising a second binding site capable of recognizing and binding c-erb-2, 145kD, 275kD, 40kD, 60kD, 100kD, 42kD, 55kD, 66kD, 75kD, 80kD, glycolipid, HMW mucin, HMW mucin II and p-glycoprotein. Applicant is required to select a bispecific antibody having specificity for a single cancer antigen for examination. The species of bispecific antibodies encompassed in claim 6 differ structurally and functionally. The examination of the different species would require different searches.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 5, and 15 are generic.

4. Upon the election of Group III, further elections of species are required as follows:

Bispecific antibodies with the second antigen binding site directed to the viruses HIV, HAV, HBV, HCV, HPV, HSV and CMV. Applicant is required to select a bispecific antibody having specificity for a single virus for examination. The species of bispecific antibodies encompassed in claim 11 differ structurally and functionally. The examination of the different species would require different searches.

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Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 10 and 15 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Lucas

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whose telephone number is (703) 308-6838. The examiner can normally be reached on M-F from 8:00 to 6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4065.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

John M. Lucas, PhD

  
March 25, 1996

  
LILA FEISEE  
PRIMARY EXAMINER  
GROUP 1800